EXHIBIT CC

Exhibit 31
Witness
Date
Reporter

ENGINEER'S REPORT

of the

JARRED BRYAN SPARKS INCIDENT

By:

Ronald J. Natoli, P.E.

and

Nancy Grugle, Ph.D.

June 26, 2014

Robson Forensic

Engineers, Architects, Scientists & Fire Investigators

A. INTRODUCTION

On June 10, 2011 Jarred Sparks died while using a Vitaeris 320 home hyperbaric chamber which was manufactured, distributed and/or processed by Oxy Health Corporation. This investigation was conducted to determine if the Vitaeris 320 home hyperbaric chamber was defective in a way that caused or contributed to the death of Jarred Sparks (Natoli) and if Oxy Health failed to provide a sufficient warning system to hyperbaric chamber users (Grugle).

B. MATERIALS AVAILABLE FOR REVIEW

- Sparks v. Oxy Health Complaint
- Sheriff's Investigation Records
- Sheriff's Investigation Photos
- Autopsy Report
- Oxy Health Vitaeris 320 Brochure
- Oxy Health Portable Mild Hyperbaric Chambers Operating and Reference Guide Rev5
- Integra Oxygen Concentrator Instruction Manual
- MAUDE Adverse Event Report: Oxy Health Corp Solace dated 10/04/2002
- Oxy Health Production Documents (OXY00001 – OXY00221
- Video from Oxy Health - Portable Mild Hyperbaric Chamber
- Defendants' Responses to Plaintiffs' First Set of Interrogatories and First Set of Requests
- for Production of Documents
- Defendants' Responses to Plaintiffs' First Set of Requests for Admission and Second Set of Requests for Production of Documents
- W.T. Workman Report dated June 3, 2014
- Dylan Sparks Deposition (pages 127 – 139)

C. BACKGROUND

C.1 The Incident

Jarred Sparks was undergoing prescribed hyperbaric chamber treatments at his home to increase oxygen in his blood to help in the treatment of his autism. Jarred had treatments for approximately twelve to eighteen months, had stopped for about one year, and then restarted again in February 2011. The Sparks family members had administered the treatments, and had over 100 hours of documented use with the incident hyperbaric chamber.

The incident hyperbaric chamber was an Oxy Health Model Vitaeris 320 mild hyperbaric chamber. The Sparks purchased the unit from Janet Presson/A Small Miracle in February 2011. The Oxy Health Model Vitaeris 320 was set up in an upstairs bedroom at the Sparks' residence. This required the removal of a dresser from the bedroom to accommodate the Oxy Health Model Vitaeris 320.

On June 9, 2011 at approximately 11:00 pm, Jarred's brother, Dylan Sparks, placed Jarred in the Oxy Health Vitreous 320 hyperbaric chamber. Dylan turned on the Oxy Health Model Vitaeris 320 air compressors which were already connected to the hyperbaric chamber bladder, inflated the chamber, recalled hearing the air relief valves actuate, and then exited and closed the bedroom door. At

approximately 3:30 am on June 10, 2010, Amy Spark entered the bedroom to remove Jarred from the chamber and found the chamber deflated and Jarred unresponsive.

Emergency services were called immediately. Dylan provided CPR until emergency personnel arrived. Jarred did not respond to resuscitation attempts and local detectives were also dispatched to conduct an investigation.

D. INSPECTION AND TESTING

D.1 The Oxy Health Mild Hyperbaric Chamber

The Oxy Health Model Vitaeris 320 is a portable hyperbaric chamber that allows the mild hyperbaric chamber to easily fit and be used in an office setting, clinic, or at home. The Oxy Health Model Vitaeris 320 has a:

- durable double sided 44 oz. urethane coated polyester bladder
- dual (redundant) steel air exchange/regulator valves
- double reinforced zippers
- internally and externally accessible air pressurization/depressurization valve
- windows/view ports
- 10 ft. medical grade dual pump hose with quick disconnect valves
- two double head oil-less 1/4 hp compressors with dual air intake filters
- two high efficiency inline air filtration rated at 0.01 microns

Per the Oxy Health Operating and Reference Guide, "**No specialized training is required** to operate the portable mild hyperbaric chamber". The Oxy Health Model Vitaeris 320 should be set up in an air-conditioned or well-ventilated room.

The pump set of the Oxy Health Model Vitaeris 320 entails the following:

1. Attach the two HIGH-EFFICIENCY AIR FILTERS to their respective compressor connections at the sites labeled "ATTACH FILTER HERE". As shown above, turn the filters clockwise to tighten. Both filters should remain in vertical positions.
2. Attach both short ends of the "Y-SHAPED" HOSE to each filter at the connector ends labeled "COMPRESSOR END.
3. Find a power outlet that will not be disturbed during the time of treatment and plug in COMPRESSOR POWER CORDS for each pump.
4. Attach the other end of the hose, which has a QUICK-RELEASE CONNECTOR HEAD to the chamber.

After initial setup of the chamber and pump, the operation of the Oxy Health Model Vitaeris 320 entails the following steps:

1. Close the INNER ZIPPER first, ensuring complete closure by lifting up the GASKET and pushing the ZIPPER SLIDER all the way to the end. The ZIPPER HEAD should be laid flat in order to avoid buckles in the GASKET. Both persons inside and outside the chamber should assist the completion of the closure inside to assure that it is airtight.
2. Lay the two (2) GASKET FLAPS flat (one at a time) and tuck them under the WHITE OUTER ZIPPER FLAP at the CREASE between the TOP ZIPPER FLAP and the CHAMBER BODY. Make sure that there are no bumps or buckles in the GASKET to ensure a proper seal. Carefully smooth out any wrinkles in the RUBBER AIR-SEALING GASKET by using a massaging motion with the hands over the GASKET FLAPS. Then close the OUTER ZIPPER a few inches at a time to make sure the GASKET is completely smooth and flat. Again, massage the GASKET FLAPS over the INNER ZIPPER to ensure a tight seal.

3. From outside the chamber, turn the PRESSURIZATION/DEPRESSURIZATION VALVE clockwise until it stops turning. If this valve is not screwed tightly enough, the chamber will not attain or maintain full pressure. Be careful not to screw the valve too tightly as this will strip or break the THREADING.

The chamber will inflate to a pressure of approximately 4 psi.

Per the Oxy Health Operating and Reference Guide, the Model Vitaeris 320 is equipped with two, stainless steel RELIEF VALVES – one as a regulator and the other as a redundant backup. Fresh air is constantly pumped into the chamber while 'old' air is exhausted via these RELIEF VALVES (AIR EXCHANGE VALVES) to eliminate carbon dioxide buildup. These valves also regulate (limit) the pressure in the chamber. Both relief valves will begin to release air at approximately 4 PSI and will continue to release air during operation. Valves are pre-set at the factory and are calibrated with the provided compressor system.

D.2 Testing the Oxy Health Mild Hyperbaric Chamber

A product inspection and testing was completed at *A Small Miracle*, 466 Lickstone Rd., Waynesville NC on January 8, 2014 by Ronald J. Natoli, P.E. At the time of the inspection the Oxy Health Vitaeris 320 had been removed from the Sparks residence and taken to A Small Miracle for our inspection. The overall unit was inspected and compared to the information found in the Operating and Reference Manual. The following items were noted during the inspection:

The unit consisted of:

- the main body (bladder) with bolsters
- an internal support frame
- an internal mattress
- a dual Gast Manufacturing oilless diaphragm air compressor assembly
- pressurization/ventilation air hose with "thumb-style" quick disconnect push-button connectors
- SeQual Integra Oxygen Concentrator
- supplemental oxygen supply hose with threaded style connectors and a clear silicone mask
- two bladder mounted pressure relief valves (S/N's 6600 & 6624)
- one bladder mounted 0 to 5 psi pressure gage
- one deflation valve with double know assembly for internal or external operation

The air compressors and oxygen generator each had their own power supply cords. The only control for the compressors was an On/Off switch. A separate wall control box was provided by Oxy Health with a wireless remote to turn power/On/Off at the wall box. Normally the compressors were plugged into the wall box for ease of operation; however this was not required to operate the compressors. Each compressor included a discharge air filter with the downstream connector being a valved insert connection. This connection existed at the discharge of each filter/compressor as well as the supply connection at the hyperbaric bladder. The connecting hose was 3/8" ID x 5/8" OD and consisted of a "Y" fitting with two quick disconnect valved bodies to connect to each filter/compressor outlet. The other end of the connecting hose had a single quick disconnect valved body to connect to the bladder mounted valved insert. The valve body connection was noted as a Colder Products Co., MPLS, MN – USA product.

The oxygen concentrator was a SeQual Integra Oxygen Concentrator Model 6323. The unit consisted of an On/Off switch and a flow adjustment knob. The oxygen flow display had a range of 0 liters/min to 10 liters/min. The unit operated at 4.5 liters/min when it was turned on. A 3/16" poly-tube with a threaded style thumb-wheel connected the supply tube to the concentrator. The polytube passed through the bladder and was connected to a clear silicone breathing mask. With only the oxygen concentrator operating the "semi-inflatable" state is achieved but the hyperbaric chamber is not pressurized.

A run test was accomplished with the compressor operating. The hyperbaric chamber bladder reached 4 psig in approximately 4 minutes. During this time the first pressure relief valve was actuated at approximately 3.5 psig. Maximum pressure was achieved at 4.1 psig in 4 minutes and 40 seconds.

Two deflation tests were conducted. First the bladder was filled to the maximum 4.1 psig reading. With the air compressors turned off, the air supply hose disconnected at the bladder and the oxygen concentrator operating, the following information was recorded:

Pressure	Time	Pressure	Time	Pressure	Time	Pressure	Time
4.1	0	3.8	30 sec	3.7	1	3.6	2
3.55	3	3.51	4	3.55	5	3.48	6
3.46	7	3.43	8	3.41	9	3.40	10
3.40	11	3.40	12	3.40	13	3.40	14
3.40	15	3.40	20				

*All pressure readings are approximated and in psig; all time recordings are in minutes unless noted.
** Oxygen concentrator running, air compressors disconnected from bladder.

The second deflation test was conducted in the same manner; however the oxygen concentrator was not operated. The following information was recorded:

Pressure	Time	Pressure	Time	Pressure	Time	Pressure	Time
4.1	0	4.0	7 sec	3.9	15 sec	3.8	30 sec
3.7	45 sec	3.6	80 sec	3.50	2 min 13 sec	3.45	2 min 54 sec
3.4	3 min 44 sec	3.3	5 min 23 sec	3.2***	7 min 34 sec***	3.1	11 min
3.0	14 min 33 sec	2.9	18 min 6 sec	2.8	21 min 40 sec	2.7	25 min 45 sec
2.65	28 min 57	2.6	32 min 5 sec	2.5	36 min 35 sec	2.4	41 min 38 sec
2.3	49 min 30 sec	2.2	54 min 17 sec	2.1	1 hr 30 sec	2.0****	1 hr**** 90 sec
2.0	1 hr 10 min 42 sec						

*All pressure readings are approximated and in psig; all time recordings are as noted.
** Oxygen concentrator off, air compressors disconnected from bladder.
*** Relief vent S/N 6600 stopped venting
****Relief vent S/N 6624 stopped venting

Testing confirmed that the incident Oxy Health Model Vitaeris 320 would maintain 4.1 psig with the compressors operating and connected to the hyperbaric chamber.

The following labels/tags were noted on the outside of the Oxy Health Model Vitaeris 320:

CAUTION: DO NOT OPEN ZIPPERS UNTIL CHAMBER IS FULLY DEPRESSURIZED

CAUTION: DO NOT INFLATE WITH ENRICHED OXYGEN

OPERATION PRESSURE 4 PSI. PROOF TESTED TO 6 PSI. P/N 15C37179/32
MANUFACTURING DATE 10/07/05
PATENT NOS. US 4,974,829; 5,398,678; 5,678,543.
Canada 1,305,012. Austria 88,080T. Germany 3,880,165; 69022986D. European 0277787; 0469071.
SERIAL NUMBER 3398

E. ANALYSIS

E.1 Use of the Oxy Health Model Vitaeris 320 Hyperbaric Chamber

Danger is a combination of hazard and risk. In the case of the Oxy Health Model Vitaeris 320, there is a risk of asphyxiation when a person is in the chamber and the chamber is sealed. A constant supply of fresh air is required to minimize the risk of asphyxiation. It is well known that elevated carbon dioxide levels are a hazardous situation that can cause asphyxiation and injury or death. It is also known that occupying a confined space without proper ventilation or fresh air increases the risk of asphyxiation and creates a dangerous condition.

Within the Safety Considerations: Precautions and Contraindications Section of the Oxy Health Operating and Reference Guide, Oxy Health states that:

> The person inside of the mild hyperbaric chamber is in an enclosed structure and is expiring carbon dioxide. This carbon dioxide is concentrated to a level that is determined by the rate at which fresh air is pumped into the chamber and released through the two air release valves.
>
> Acceptable levels for exposure to carbon dioxide have been determined based on time of exposure as described in the following table:

Duration (Hours)	Carbon Dioxide Level (Percent)
1	3
24	1

> As long as the CHAMBER COMPRESSOR is "ON" and running, fresh air will be introduced into the chamber and the equilibrium value for carbon dioxide concentration will remain at **less than one percent (1%)**

The air quality inside the Oxy Health Model Vitaeris 320 is intended to be maintained by the constant supply of fresh air by the attached compressors. As stated in the Oxy Health Operating and Reference Guide, fresh air is constantly pumped into the chamber while 'old' air is exhausted via the dual relief valves (air exchange valves) to eliminate carbon dioxide buildup. Oxy health knew that a loss of fresh supply air or a reduction in fresh supply air to an operating and occupied Oxy Health Model Vitaeris 320 would cause an increase in the carbon dioxide concentration and the "less than one percent (1%)" equilibrium would not be maintained.

OSHA Hazard Information Bulletins warn that carbon dioxide is an asphyxiant and that concentrations of 10% (100,000 ppm) or more can produce unconsciousness or death.

Susan A. Rice, Ph.D., D.A.B.T., author of "HUMAN HEALTH RISK ASSESSMENT OF CO_2: SURVIVORS OF ACUTE HIGH-LEVEL EXPOSURE AND POPULATIONS SENSITIVE TO PROLONGED LOW-LEVEL EXPOSURE" states that "with high-level CO_2 exposure, the displacement of O_2 by CO_2 significantly contributes to toxicity. Signs of asphyxia are evident when the atmospheric O_2 is ≤16% [1]. Almost immediate unconsciousness leading to death occurs in humans at rest when the O_2 is reduced to 10 to 13%. Strenuous physical exertion increases the threshold [2]."

CO_2 – Indoor Air Consequences by Dr. Stacy L. Daniels warns that:

- The main effect of CO_2, involves its ability to displace oxygen within a confined space.
- As oxygen is inhaled, CO_2 levels build up in the confined space, with a decrease in oxygen content in the available air.
- Being 1.5 times as dense as air, CO_2, accumulates in low areas.
- According to ACGIH, 1998; Bright et al., 1992; Hill, 1992; NIOSH, 1987, Most indoor air complaints eliminated, used as reference for air exchange for protection of children at 600 ppm (0.06%)

Oxy Health knew with an occupant inside the Oxy Health Model Vitaeris 320 chamber with the chamber bladder zipper sealed, a lack of fresh supply air from an inoperable compressor or disconnected supply hose would cause an increase in carbon dioxide inside the chamber and create a dangerous condition.

E.2 Cause of the Incident (Natoli)

The Sheriff's Investigation Report, Sheriff's Investigation Photos and Medical Examiner's Report were reviewed. According to the Sheriff's report, Dylan turned on the compressors which were already connected to the hyperbaric chamber bladder, turned on the oxygen machine, and pushed the chamber back against a book shelf so that he could close the door to the bedroom. The Sheriff's Report and the testimony by Dylan Sparks (p138; Feb 21, 2014) stated that the "pressure valves" at the bottom were heard venting by Dylan Sparks. In order for the pressure valves to be venting, the air compressors were operating and the Oxy Health Vitaeris 320 had inflated. Testing of the incident chamber indicated that relief vent S/N 6624 would vent at a pressure above 2.0 psig and relief vent S/N 6600 would vent at a pressure above 3.2 psig. Based on the Sheriff's Report and testimony from Dylan Sparks, the supply air hose was connected to the Health Model Vitaeris 320 chamber and the compressors were operating when Dylan Sparks placed Jarred Sparks in the chamber and sealed the chamber bladder zipper.

Detective Mincey noted that when he arrived, the air tube that supplies pressure/fresh air to the chamber was disconnected and coiled on the floor (See Photos 1 & 2).

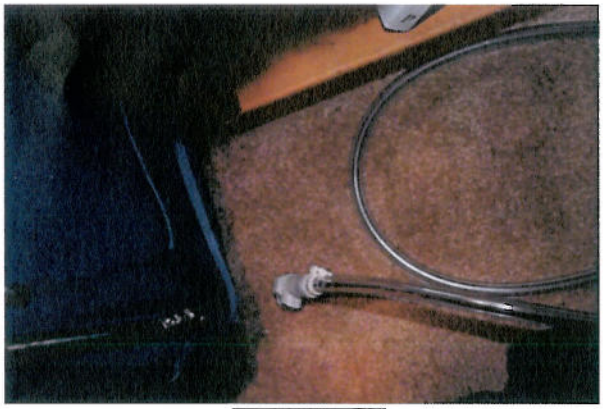


Photo 1

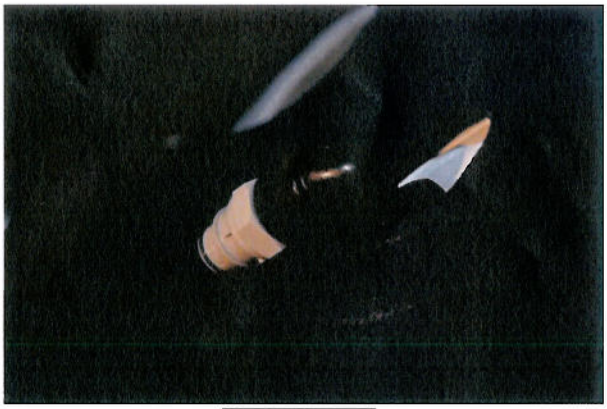


Photo 2

The second smaller tube that supplied oxygen was still connected. The detective's investigation revealed that a clear plastic container containing miscellaneous items inside was on the book shelf (see Photo 3).

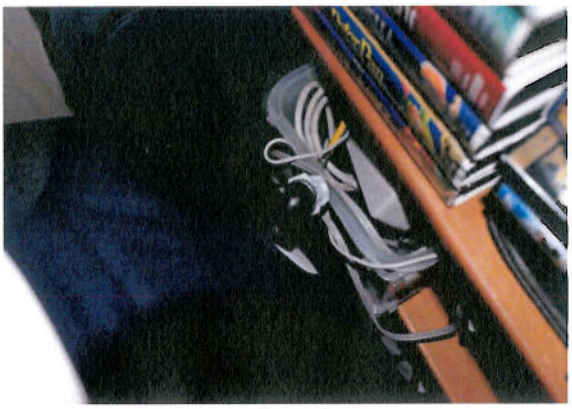


Photo 3

Photo 4

When referring to the quick disconnect connection (see Photo 4 – Jan 8, 2014 inspection photo) supplied with the Oxy Health Vitaeris 320, the detective reported that "the button subsequently was being pressed by the clear plastic container lip" (see Photo 3).

The air hose was connected to the chamber and the unit was pressurized by the detectives. Lieutenant Reyes "touched" the air hose quick disconnect button, the connection disengaged and the hose fell to the floor in a coil as previously noted. The detective's investigation "revealed that the hose that pumped air into the chamber had a push release button, the hose was located on the back of the chamber, and when the chamber was pushed against the book shelf, the button became pushed by a clear plastic container lip sitting on the bookshelf". The Detectives concluded that the clear plastic container had inadvertently depressed the release button on the quick release button allowing the critical supply air to the chamber to be disconnected. The loss of the critical supply of fresh air to the chamber would not allow the chamber interior to be maintained at the equilibrium value for carbon dioxide of less than 1% as stated by Oxy Health in the Oxy Health Operating and Reference Guide.
The Office of the Chief Medical Examiner, based on the autopsy and investigative findings, opined that "the cause of death was asphyxiation secondary to the collapse of the chamber".

An inadvertent disconnection of the quick disconnect valve interrupted the supply of fresh air to the Oxy Health Model Vitaeris 320 hyperbaric chamber. The disconnection of the quick disconnect valve allowed the buildup of carbon dioxide within the Oxy Health Model Vitaeris 320 hyperbaric chamber, causing the death by asphyxiation of Jarred Sparks

E.3 Manufacturer's Responsibilities (Natoli)
Danger is a combination of hazard and risk. It is well known that elevated carbon dioxide levels are a hazardous condition that can cause asphyxiation and injury or death. It is also known that occupying a confined space without proper ventilation or fresh air is a dangerous condition. Oxy Health knew that the hazard of asphyxiation from elevated carbon dioxide levels existed during the use of the Oxy Health Vitaeris 320 hyperbaric chamber.

Manufacturers have a responsibility to protect people from hazards that may be present in their products. The design process must take into account the types of actions that people make under reasonably foreseeable conditions of service, including both intended use and reasonably foreseeable misuse.

The American Society of Mechanical Engineers publishes a standard, ASME PVHO-1-2002 Pressure Vessels for Human Occupancy that details the requirements for the design, fabrication, inspection, testing, marking and stamping of pressure vessels for human occupancy having a differential pressure exceeding 2 psig. ASME PVHO-1-2002 is a recognized safety standard as well as a requirement for manufacturers to follow per the FDA - Food and Drug Modernization Act (1997).

Additionally, the National Fire Protection Association (NFPA) Standard 99, Standard for Healthcare Facilities (2005), Chapter 20 – Hyperbaric Facilities is another recognized safety standard and has also been a recognized standard under the FDA - Food and Drug Modernization Act (1997).

The book *"Product Safety Design for Managers; 1984"*; Authored by R. Matthew Seiden, P.E., page 7, describes the hierarchy. The following is the well recognized and accepted hierarchy of safe product design:

Rules of Practice for Safe Design

Principle One: Hazard Elimination.
If practical, design the hazard out of the product, workplace, job, or facility through engineering means.

Principle Two: Safety Guards and Enclosures.
If you can't eliminate the hazard entirely, enclose or guard it at its source to protect the user.

Principle Three: Safety Warnings and Instructions.
If you can't guard the hazard, warn or instruct the user as to dangers of the product under reasonably foreseeable conditions of service and commerce.

E.4 Oxy Health Vitaeris320 Hyperbaric Chamber Defects (Natoli)

Oxy Health knew that the hazard of asphyxiation from elevated carbon dioxide levels existed during the use of the Oxy Health Vitaeris 320 hyperbaric chamber. Oxy Health knew that the chamber compressor needed to be "ON" and running and that fresh air had to be introduced into the chamber as designed in order to maintain an equilibrium value for carbon dioxide concentration at less than one percent (1%). Oxy Health knew that a loss of fresh supply air or a reduction in the amount of fresh air supply would cause an increase in the concentration of carbon dioxide when the Oxy Health Vitaeris 320 hyperbaric chamber was occupied.

Quick disconnect fittings, such as the incident fitting on the Oxy Health Vitaeris 320 hyperbaric chamber, allows a person to make and break tubing connections without separating the tubing from the fitting. A quick disconnect, provides a means of quickly disconnecting a line without the loss of fluid or entrance of air into a system. The quick disconnect consists of a coupling assembly with two halves. Each half contains a valve held open when the coupling is connected. When the coupling valve is open, it allows air to flow through in either direction. When it is disconnected, a spring in each half closes the valve, preventing the loss, flow or entrance of air. This happens quickly, shutting the system down almost immediately – hence, the name *quick disconnect*.

Any organization that: designs, manufactures, assembles, markets, distributes, and/or sells a hyperbaric chamber has a duty to ensure that component parts, such as quick disconnect valves for the air supply, are reasonably safe for their intended use.

Quick disconnect couplings are designated as connecting devices designed to permit easy and immediate connection and separation of air or fluid for pneumatic or hydraulic lines without the need for tools. When a person has to stop and grab a tool in order to disconnect, it takes time and manpower. When installed in a fluid system, quick disconnect couplings save time by eliminating the need for system

bleeding, recharging, or purging of air due to a lag time in the disconnection process. There were no concerns for saving of manpower, bleeding air out of lines, purging trapped air or recharging of any fluid in the supply air hose for the Oxy Health Vitaeris 320 hyperbaric chamber. The benefits of using a quick disconnect for the air supply connections on the Oxy Health Vitaeris 320 was the simplicity of not requiring a special tool and speed of setup.

The detriment of a quick disconnect such as the incident quick disconnect, is that it requires no tools to disengage the latching system, is simple to operate, and can inadvertently become disengaged if the release is accidentally depressed. This type of connector is not proper where the security of the connection is a safety issue. In the design of products, speed and simplicity is secondary to safety.

The Manufacturer and User Facility Device Experience (MAUDE) database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers. Medical Device Reporting (MDR) regulation, 21 CFR Part 803 (July 31, 1996) requires manufacturers, importers, device user facilities and distributors to report certain device-related adverse events and product problems to the FDA. These reportable incidents include deaths, serious injury, or device malfunction (21 CFR Part 803.10c). Additionally, the term "manufacturer" includes any person that manufacturers, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure (21 CFR Part 803.3). Oxy Health is recognized as a manufacturer of hyperbaric chambers.

According to discovery document MR_Sparks 000098, a MAUDE report was filed on 10/4/2002 for the Oxy Health Model Solace Hyperbaric Chamber. Oxy Health Operating and Reference Guide Revision 3 (dated August 2003), lists the Solis 210, Respiro 270 and the Vitaeris 320 as the three hyperbaric chamber models offered. These same three models are included in later revisions of the Oxy Health Operating and Reference Guide. All provided Oxy Health Operating and Reference Guides were reviewed and found that all offered hyperbaric chambers used the same style disconnect valve assembly at the compressor and bladder end. The basic operation of the quick disconnect function did not change, however, earlier models used a different style quick disconnect connector at the compressor end only.

The 10/4/2002 MAUDE report states that:

> "The international congress on hyperbaric medicine (ichm) is holding their tri-annual scientific meeting. The oxyhealth corp has two portable, fabric mild hyperbaric chambers on display: the vitaeris 320 and the solace personal health system. Their exhibit is physically located immediately across the room from the rptr's display. At approx 1030 hrs, one of the oxyhealth corp sales rep was preparing the solace personal health system for a demonstration dive for one of the delegates. When the sales rep was attempting to connect the air compressor to the chamber there was a loud pop. Rptr was at their display immediately across the room from the oxyhealth exhibit talking with two other meeting delegates. After hearing the pop they looked up to see the sales rep looking around the floor for something. Rptr looked down to discover a plastic quick disconnect valve on the floor approx two feet from where they were standing. Rptr presumes that the valve was not connected properly and the popping sound heard was the valve as it disconnected after initial pressurization. Further, rptr assumes that it was propelled across the room and bounced to the floor after hitting the back drape of the display booth. Rptr does not know the amount of pressure at the time of failure. Rptr picked up the valve and gave it back to the sales rep. The sales rep simply thanked rptr for giving it back."

The Code of Federal Regulation Title 21 Food and Drug Part 820 – Quality System Regulation defines a "Complaint" as any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. As part of the Quality System (Title 21Part 820) requirements, Oxy Health was to

establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. Any complaints should have triggered an internal review of the design and the use of the quick disconnect valve as required per Section 820.100 - Corrective and Preventative Action.

Oxy Health knew on October 4, 2002 that the quick disconnect style valve used on their hyperbaric chambers could inadvertently disconnect.

The hazard of an inadvertent disconnection of the quick disconnect valve and interruption of the supply of fresh air to an occupant of the Oxy Health Model Vitaeris 320 hyperbaric chamber was known by Oxy Health. This hazard made the Model Vitaeris 320 hyperbaric chamber dangerous and unsuitable for its intended purpose and was a cause of Jarred Sparks' asphyxiation.

E.5 Design Changes That Would Have Made the Oxy Health Vitaeris320 Hyperbaric Chamber Safer (Natoli)

A critical system, such as the supply air system on the Oxy Health Model Vitaeris 320 hyperbaric chamber, should have redundant components and positive or locking style connections to minimize the risk of an inadvertent disengagement and loss of supply air. The Oxy Health hyperbaric chamber literature boasts of "dual-redundant steel air-exchange/regulator valves". These valves are part of the pressure control and supply air system. However, this is the only critical component that appears to be redundant in the design.

The Oxy Health Model Vitaeris 320 hyperbaric chamber has a constant air flow design which, according to the Oxy Health Operating and Reference Guide, as long as the chamber compressor is "ON" and running, fresh air will be introduced into the chamber and the equilibrium value for carbon dioxide concentration will remain at less than one percent (1%). In keeping with the main design intent, there were a number of possible design changes and guards that would have prevented a loss of supply air and increase in carbon dioxide levels within the Oxy Health Model Vitaeris 320 hyperbaric chamber.

Hazard Elimination

ASME PVHO-1-2002 does not specify the types of approved fittings in 2002, however Section 4-4.5.1.(d) Hose Materials - Fittings states that "Fittings used on divers' umbilical shall be types which are resistant to inadvertent disengagement". The need for a secure, and positive latching connection on critical air systems was noted. In 2007, ASME PVHO-1-2007 clarifies in Section 4- 2.4.1 (*f*) Nonmetallic Materials – fittings "fittings used on life critical breathing devices shall be of types that are resistant to inadvertent disengagement".

A simple design would have been to incorporate a threaded style connector (see Photos 5 & 6). This style connector is available readily in a "valved" body and "valved" insert configuration similar to quick disconnect style currently being used on the Oxy Health Model Vitaeris 320 hyperbaric chamber.

Unlike the incident quick disconnect valve currently being used, the threaded valve requires 2-1/2 to 3-1/2 full turns of the valve ring to disengage the spring loaded connection. And like the existing quick disconnect valve, connections are made quickly, easily and without the use of tools. The use of a threaded style valved connection would have minimized the risk of an inadvertent release of the critical supply air connection.

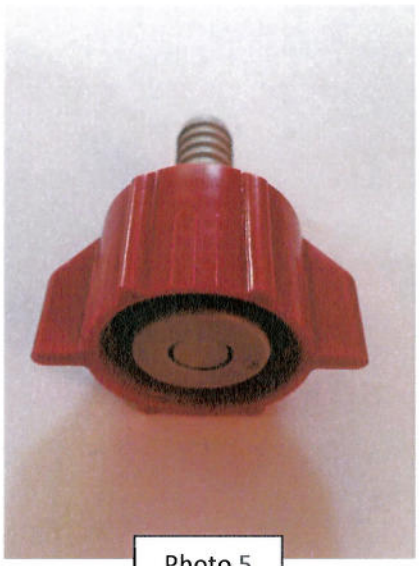


Photo 5

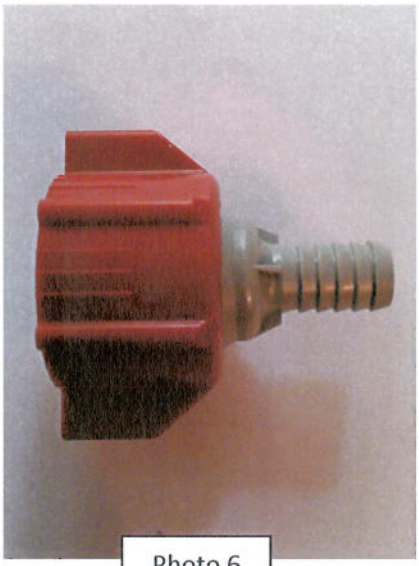


Photo 6

Without the use of a positive locking or threaded style connector, the Oxy Health Model Vitaeris 320 hyperbaric chamber was defective, unreasonably dangerous, unsafe for its intended use, and a cause of Jarred Sparks' asphyxiation.

Guard the User

Monitoring devices are common devices used to reduce or eliminate the risk of exposure to a hazard. NFPA Standard 99 (2002 Edition), Standard for Healthcare Facilities (2005) , Chapter 20 – Hyperbaric Facilities classifies the Oxy Health Model Vitaeris 320 hyperbaric chamber as a Class B - Human, single occupancy chamber.

Specifically NFPA 99 – 2002 requires the following:

> 20.2.8.5 Carbon Dioxide Monitoring. The chamber atmosphere shall be monitored for carbon dioxide levels during saturation operations whenever ventilation is not used.

Although, carbon dioxide monitoring is only required during saturation operations, which is not part of the operation sequence of the Oxy Health Model Vitaeris 320 hyperbaric chamber, NFPA recognizes the importance of monitoring and maintaining good breathing air quality. Carbon dioxide monitors and alarms are readily available in basic stand-alone or remote monitoring configurations. Many have adjustable warning levels and can also log carbon dioxide levels over time and download the information to a computer. One such simple solution, which is sold for $109, is shown in figure A:

Figure A

Oxy Health had a responsibility to identify hazards associated with the Oxy Health Model Vitaeris 320 hyperbaric chamber and to provide guarding to minimize the risk of injury. It would have been easy for Oxy Health to provide guarding that would have monitored the carbon dioxide (CO_2) levels within the chamber and also alarmed in the event that elevated carbon dioxide levels within the hyperbaric chamber were detected. Through the use of a simple carbon dioxide monitor, Oxy Health should have alerted the Sparks of a hazardous condition and prevented the carbon dioxide levels from reaching a dangerous level.

Without the use of a guard (carbon dioxide monitoring system), the Oxy Health Model Vitaeris 320 hyperbaric chamber was defective, unreasonably dangerous, unsafe for its intended use, and a cause of Jarred Sparks' asphyxiation.

E.6 Failure to Warn (Grugle)

As a manufacturer of the hyperbaric chamber, Oxy Health had a duty to design and provide an adequate product warning system to alert all product users to the hazards associated with the hyperbaric chamber. Specifically, Oxy Health had a duty to warn users about the asphyxiation hazard, the potential for the quick-disconnect valve to be easily and inadvertently disconnected, and to instruct users how to avoid unintentionally disconnecting the air pressurization tubing that supplies fresh air to the hyperbaric chamber (1,2,9).

The purpose of a warning is to improve safety or to eliminate or reduce incidents that result in injury, illness or property damage by influencing people's behavior in ways that will improve safety. Warnings are intended to provide information that enables people to understand hazards, consequences and appropriate/inappropriate behavior which, in turn, enables them to make informed decisions (1,2). Warnings should be provided when a significant hazard exists from foreseeable use of a product. The warning should provide information about the hazard, the consequences of exposure to the hazard, and how to avoid the hazard. A warning should be provided to everyone who may be exposed to the hazard and everyone who may be able to do something about the hazard.

E.6.1 Effective Warnings

An effective warning system is necessary to ensure potential users are notified about the hazards associated with the use of the product, understand the consequences of the hazard, and take the appropriate steps necessary to avoid the hazard. Failure to provide effective warning denies users the opportunity to protect themselves from foreseeable harm.

Effective warnings should be (1-5,7,8):

- Available at time and location needed
- Conspicuous
- Explicit

Warnings must be available at a time and location needed so the user has access to the critical information. A warning is of little use if it is not available to the intended user. Warnings must be conspicuous and attract attention so that the users can distinguish critical safety information from unimportant or irrelevant information and give it the attention required. Warnings must be explicit so that the user understands exactly what the hazard is and exactly what steps to take to avoid the hazard. Ambiguous warnings are confusing and prevent the user from taking appropriate action. Warnings need to be practical, convenient, and possible. If the warning is not practical, the user may not be able to comply or may not be motivated to comply. Warnings must be comprehensible to ensure the user understands the hazard, how to avoid it and the consequences of not avoiding the hazard. Effective warning systems improve safety and reduce incidents that result in injury, illness or property damage.

Oxy Health failed to provide effective warnings that were available at the time and location needed, conspicuous, and explicit.

Available

Oxy Health failed to provide any information related to the hazards associated with the inadvertent release of the quick-disconnect valve at the time and location needed by product user (i.e., on the product). The only information related to the valve was provided in the Operating and Reference Guide.

Hazards leading to more severe consequences and/or those more likely to occur should be included on an on-product warning label. On-product warnings are used to ensure critical safety information is available when and where needed (i.e., during use). Collateral material can be lost, overlooked, disregarded, or forgotten, depriving the user of all warning information about the product at the time the information is needed. Instruction manuals are often not available, not retained, and not read, particularly by persons experienced or familiar with the product or similar products.

Explicit

Oxy Health failed to provide warning information that was explicit. Explicit information is needed so that the user can identify the specific hazard, recognize the steps needed to avoid the hazard, and understand the full consequences of encountering the hazard so they are motivated to comply with the warning. The instructions and safety information provided by Oxy Health in their Operating and Reference Guide failed to provide clear, detailed, and complete information. The information provided by Oxy Health in their manual only partially communicated the hazards.

The Operating and Reference Guide instructs users to "Make sure the intake hose is connected securely to the intake valve. Turn "on" the compressor and leave "on" for the duration of treatment." It also states "There should be no air leak from the quick disconnect valves." The instructions fail to explicitly warn users that the quick-disconnect valve can be inadvertently disconnected and that a disconnected pressurization valve will result in a loss of fresh air to the chamber and possible asphyxiation and death. The instructions also fail to explicitly identify the possibility that the quick-disconnect button on the pressurization valve could be unintentionally disconnected by an object (e.g., wall, bookshelf) being

pushed up against the release button. Furthermore, the guide fails to explicitly communicate how the user can avoid the hazard (e.g., make sure the quick-disconnect button cannot be unintentionally pressed by an adjacent object).

The "Excessive Carbon Dioxide Exposure" section of the Operating and Reference Guide provides a table of acceptable levels for exposure to carbon dioxide and then states that as long as the chamber compressor is on and running, the carbon dioxide concentration will remain at less than 1%. As written, this information simply tells a user that if the compressor is turned on, a user will not suffer from excessive carbon dioxide exposure above the acceptable levels in the table and that "as long as the chamber compressor is on and running, fresh air will be introduced into the chamber." This is an incorrect statement because the air cannot flow into the chamber if the tubing from the compressor to the chamber is disconnected. The information does not identify the asphyxiation hazard that result from a disconnected valve, explain the consequences of excessive carbon dioxide exposure (e.g., death), or correctly instruct the user how to avoid the asphyxiation hazard (i.e., ensure pressurization valve is connected and cannot be inadvertently disconnected).

Oxy Health failed to provide explicit warning information to users of the product regarding the asphyxiation hazard associated with the quick-disconnect coupling. Without the safety information, users were deprived of critical asphyxiation hazard information and the information needed to properly and safely use the hyperbaric chamber.

Conspicuous

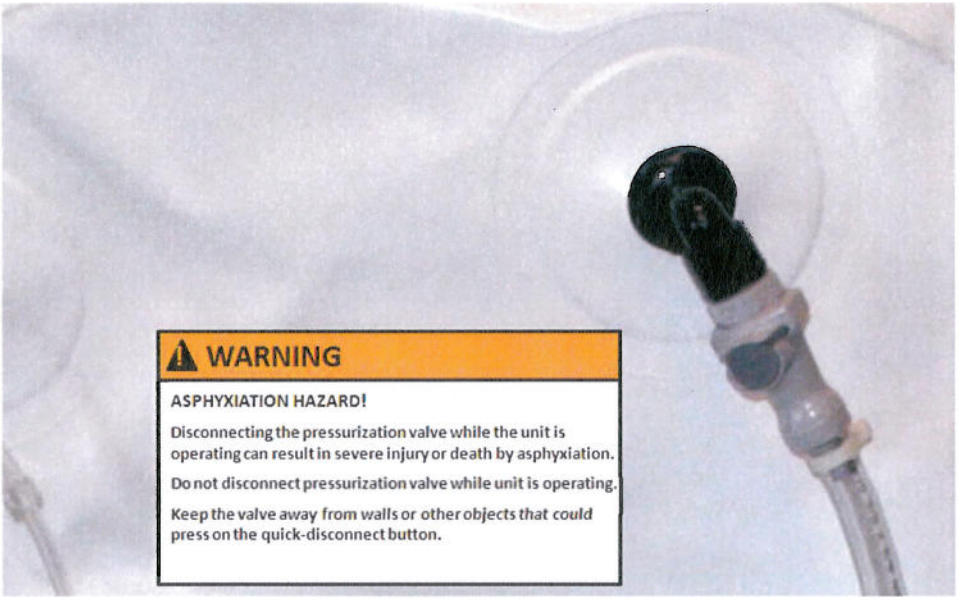
Inconspicuous warnings are less likely to be noticed, read, and acted upon. They also appear less important than conspicuously displayed warnings whereas conspicuous warnings draw the user's attention, emphasize importance compared to background information, and are more likely to be attended to and acted upon.

Critical safety information must be conspicuously identified as such. Standards exist for the formatting of product safety warnings. For example, ANSI Z535.4 states that a warning should possess a signal word panel and message panel. The signal word panel presents the safety alert icon (exclamation point in triangle) and signal word (for example, WARNING) in black print on a safety orange background. The formatting of the warning draws the user's attention and identifies it as important safety information. The American National Standard ANSI Z535.6-2006 Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials is a standard published by the National Electrical Manufacturer's Association. ANSI Z535.6-2006 sets forth a standard for a hazard communication system specifically for product safety information in collateral materials such as the Operating and Reference Guide and states that safety messages should identify the hazards, indicate how to avoid the hazards, and advise of the probable consequences of not avoiding the hazards. They should be preceded by a safety symbol or a signal word panel.

Oxy Health failed to conspicuously identify asphyxiation warning information on the hyperbaric chamber or in the Operating and Reference Guide. There were no warning labels related to the quick-disconnect valve affixed to the hyperbaric chamber itself. The safety and precautions section of the Operating and Reference Guide lists excessive carbon dioxide exposure under "safety considerations," but the guide does not use a signal word such as "Warning" or other graphical means to identify the information as critical safety information. Oxy Health's failure to conspicuously present critical safety information reduced the likelihood that users would notice the information or identify it as critical safety information.

Oxy Health should have provided an on-product warning about the asphyxiation hazard resulting from unintentional disconnection of the quick-disconnect valve and provided instructions telling the user not to push the hyperbaric chamber up against any object that might unintentionally push the quick-disconnect button. Oxy Health's failure to provide an on-product warning deprived end users of the hyperbaric chamber from having, noticing, and reading critical product warnings and from the ability to modify their

behavior as a result. The figure below is an example of an appropriate and effective on-product quick-disconnect valve warning.



Example On-Product Quick-Disconnect Valve Warning

It would have been reasonable for Oxy Health to provide an effective warning system, including readily visible, conspicuous, prominent, specific, and explicit warnings with the hyperbaric chamber. The cost in terms of money, effort, and time to do so would have been minimal and insignificant. Oxy Health should have done the following to provide an effective warning system:

- Added on-product warning information to the hyperbaric chamber
- Included additional asphyxiation hazard safety information and warnings in the Operating and Reference Guide
- Followed industry guidelines for designing the warning system content and form

Oxy Health's failure to provide an effective warning system deprived the user of critical information needed for the safe use of the hyperbaric chamber. Oxy Health's failure to provide an effective warning system was unreasonably dangerous, rendered the product defective, and was a cause of Jarred Sparks' asphyxiation.

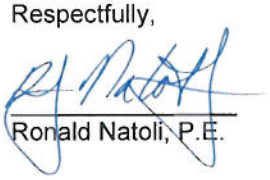
F. FINDINGS

F.1 Findings (Natoli)

Within the bounds of reasonable engineering certainty, and subject to change if additional information becomes available, it is my professional opinion that:

1. Jarred Sparks was fatally injured when he was unreasonably exposed to the hazard of asphyxiation as a result of an inadvertent release of the ventilation/pressurization air quick disconnect valve on the Oxy Health Vitaeris 320.
2. Lack of ventilation supply air or lack of a continuous fresh air supply into the enclosed bladder of the Oxy Health Vitaeris 320 makes the Oxy Health Vitaeris 320 extremely dangerous.
3. Oxy Health knew that persons using the Oxy Health Vitaeris 320 could be exposed to the danger of asphyxiation by the inadvertent release of the ventilation/pressurization supply air quick disconnect valve.
4. Oxy Health knew that the valve connections on the ventilation/pressurization supply air were a critical component to ensure that the required continuous fresh-air supply from the operating compressors was supplied to the Oxy Health Vitaeris 320 hyperbaric chamber to maintain carbon dioxide equilibrium of less than one percent.
5. Oxy Health's failure to properly identify the failure mode and effect of their quick disconnect valve assembly was a cause of Jarred Sparks asphyxiation.
6. Oxy Health knew or should have known that the inadvertent loss of the required continuous fresh air supply while operating the Oxy Health Vitaeris 320 was a hazard. This hazard made the Oxy Health Vitaeris 320 hyperbaric chamber unreasonably dangerous and unsuitable for its intended purpose.
7. Oxy Health's failure to provide threaded style or safety-locking style valve connections on the ventilation/pressurization supply air; or make other design changes to prevent or warn against the inadvertent loss of the required continuous fresh air supply, while operating the Oxy Health Vitaeris 320, was a design defect and was a cause of Jarred Sparks' asphyxiation.
8. Oxy Health's failure to provide a visual and audible indication that a dangerous level of carbon dioxide or reduction in oxygen levels exists, made the Oxy Health Vitaeris 320 hyperbaric chamber defective, unreasonably dangerous, unsafe for its intended use, and a cause of Jarred Sparks' asphyxiation.
9. The Oxy Health Vitaeris 320 hyperbaric chamber was defective, unreasonably dangerous, and unsafe for its intended use, and was a direct cause of Jarred Sparks' asphyxiation.

Respectfully,



Ronald Natoli, P.E.

F.2 Findings (Grugle)

Within the bounds of reasonable scientific certainty, and subject to change if additional information becomes available, it is my professional opinion that:

1. Oxy Health had a responsibility to design and provide an adequate product warning system to alert product users to the asphyxiation hazard, instruct users how to avoid the hazard, and to protect the users from needless danger.
2. Oxy Health failed to provide a warning system and instructions, including readily conspicuous, specific, and explicit warnings, which met applicable industry standards, guidelines, and practices regarding the asphyxiation hazard.
3. It would have been reasonable for Oxy Health to provide an effective warning system, including readily visible, conspicuous, prominent, specific, and explicit warnings with the hyperbaric chamber. The cost in terms of money, effort, and time to do so would have been minimal and insignificant.
4. Oxy Health's failure to provide an effective warning system deprived the user of critical information needed for the safe use of the hyperbaric chamber.
5. Oxy Health's failure to provide an effective warning system was unreasonably dangerous, rendered the product defective, and was a cause of Jarred Sparks' asphyxiation.

Respectfully,

Nancy L. Grugle

Nancy L. Grugle, Ph.D.
Human Factors Consultant

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